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STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10566796
Filing Date	2006-01-31
First Named Inventor	Sweeney et al.
Art Unit	None
Examiner Name	Not Assigned
Attorney Docket Number	PENN0870US.NP

**U.S. PATENTS**

Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
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	1	CA1219764			1987-03-31	Ho et al.		<input checked="" type="checkbox"/>

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1	Allen et al., "Apoptosis: a mechanism contributing to remodeling of skeletal muscle in response to hindlimb unweighting", Am. J. Physiol. 1997 273 (Cell Physiol. 42): C579-C587	<input checked="" type="checkbox"/>
2	Allen et al., "Myonuclear Domains in Muscle Adaptation and Disease", 1999 Muscle Nerve 22: 1350-1360	<input checked="" type="checkbox"/>
3	Badalamente et al., "Delay of Muscle Degeneration and Necrosis in mdx Mice by Calpain Inhibition", 2000 Muscle Nerve 23: 106-111	<input checked="" type="checkbox"/>
4	Barton-Davis et al., "Viral Mediated Expression of Insulin-Like Growth Factor I Blocks the Aging-Related Loss of Skeletal Muscle Function", Proc. Natl Acad Sci USA Vol. 95, No. 26, December 22, 1998, pp. 15603-1560	<input checked="" type="checkbox"/>
5	Billings et al., "Distribution of the Bowman Birk protease inhibitor in mice following oral administration", 1992, Cancer Letters 62 191-197	<input checked="" type="checkbox"/>
6	Birk et al., "The Bowman-Birk inhibitor", Int. J. Peptide Protein Res. 25, 1985, 113-13	<input checked="" type="checkbox"/>
7	Bodine et al., "Akt/mTOR pathway is a crucial regulator of skeletal muscle hypertrophy and can prevent muscle atrophy in vivo", Nature Cell Biology, vol. 3, November 2001, pp. 1014-1019	<input checked="" type="checkbox"/>
8	Buetler et al., "Green Tea Extract Decreases Muscle Necrosis in mdx Mice and Protects Against Reactive Oxygen Species", Am. J. Clin. Nutr. 2002; 75:749-53	<input checked="" type="checkbox"/>
9	Criswell et al., "Overexpression of IGF-I in skeletal muscle of transgenic mice does not prevent unloading-induced atrophy", Am. J. Physiol. 1998 275: E373-E379	<input checked="" type="checkbox"/>
10	Goldberg et al., "Protein Turnover in Skeletal Muscle", The Journal of Biological Chemistry, Vol. 244, No. 12, 1969 pp. 3223-3229	<input checked="" type="checkbox"/>
11	Gordon et al., "Plasticity in Skeletal, Cardiac, and Smooth Muscle Selected Contribution: Skeletal muscle focal adhesion kinase, paxillin, and serum response factor are loading dependent", J Appl Physiol 2001 90: 1174-1183	<input checked="" type="checkbox"/>

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12	Granchelli et al., "Cromolyn Increases Strength in Exercised MDX Mice", Research Communications in Molecular Pathology and Pharmacology, Vol. 91, No. 3 March 1996 pp. 287-296	<input checked="" type="checkbox"/>
13	Hornberger et al., "Regulation of translation factors during hindlimb unloading and denervation of skeletal muscle in rats", Am. J. Physiol. 2001 281:C179-C187	<input checked="" type="checkbox"/>
14	Hunter et al., "Activation of an alternative NF- $\kappa$ B pathway in skeletal muscle during disuse atrophy", The FASEB Journal, 2002 Vol. 16 pp. 529-538	<input checked="" type="checkbox"/>
15	Ikemoto et al., "Space shuttle flight (STS-90) enhances degradation of rat myosin heavy chain in association with activation of ubiquitin-proteasome pathway", The FASEB Journal published online March 12, 2001	<input checked="" type="checkbox"/>
16	Jaspers et al., "Atrophy and growth failure of rat hindlimb muscles in tail-cast suspension", The American Physiological Society, 1984 pp. 1472-1479	<input checked="" type="checkbox"/>
17	Kennedy et al., "Preparation and Production of a Cancer Chemopreventative Agent, Bowman-Birk Inhibitor Concentrate", Nutr Cancer 1993 Vol. 19, No. 3, pp. 281-302	<input checked="" type="checkbox"/>
18	Ann R. Kennedy, "Anticarcinogenic Activity of Protease Inhibitors", Protease Inhibitors as Cancer Chemopreventive Agents, edited by Walter Troll and Ann R. Kennedy. Plenum Press, New York, 1993	<input checked="" type="checkbox"/>
19	Ann R. Kennedy, "Chemopreventative Agents: Protease Inhibitors", Pharmacol. Ther. Vol. 78, No. 3, pp. 167-209, 1998	<input checked="" type="checkbox"/>
20	Larionova et al., "Inhibition of Cathepsin G and Human Granulocyte Elastase By Multiple Forms of Soybean Inhibitor of Bowman-Birk Type", Biokhimiya 1993 58:1437-1444	<input checked="" type="checkbox"/>
21	Loughna et al., "Effect of Inactivity and Passive Stretch on Protein Turnover in Phasic and Postural Rat Muscles", J. Appl. Physiol. 1986 61(1) 173-179	<input checked="" type="checkbox"/>
22	Mitchell et al., "A muscle Precursor Cell-Dependent Pathway Contributes to Muscle Growth After Atrophy", Am J Physiol Cell Physiol 281: C1706-C1715, 2001	<input checked="" type="checkbox"/>

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23	Nikawa et al., "Effects of a Soy Protein Diet on Exercise-Induced Muscle Protein Catabolism in Rats", Nutrition 18:490-495, 2002	<input checked="" type="checkbox"/>
24	Oreffo et al., "Actual effects of the Bowman-Birk protease inhibitor in mice", Toxicology, 69 (1991) 165-176	<input checked="" type="checkbox"/>
25	Sangorin et al., "Myofibril-bound Serine Protease and its Endogenous Inhibitor in Mouse: Extraction, Partial Characterization and Effect on Myofibrils", Comparative Biochemistry and Physiology Part B 131 (2002) 713-723	<input checked="" type="checkbox"/>
26	Sawada et al., "Therapeutic Effect of Carnostat Mesilate on Duchenne Muscular Dystrophy in mdx Mice", Pharmaceutical Society of Japan, 2003, Biol. Pharm. Bull. 26(7) 1025-1027	<input checked="" type="checkbox"/>
27	Solomon et al., "Importance of the ATP-Ubiquitin-Proteasome Pathway in the Degradation of Soluble and Myofibrillar Proteins in Rabbit Muscle Extracts", The Journal of Biological Chemistry, 1996, Vol. 271, No. 43, 26690-26697	<input checked="" type="checkbox"/>
28	Spencer et al., "Overexpression of Calpastatin Transgene in mdx Muscle Reduces Dystrophic Pathology", Human Molecular Genetics, 2002, Vol. 11, No. 21, pp. 2645-2655	<input checked="" type="checkbox"/>
29	Stevenson et al., "Global Analysis of Gene Expression Patterns During Disuse Atrophy in Rat Skeletal Muscle", J. Physiol. 2003;551;33-48	<input checked="" type="checkbox"/>
30	Tada et al., "Effect of Different Dietary Protein Composition on Skeletal Muscle Atrophy by Suspension Hypokinesia/Hypodynamia in Rats", J. Nutr. Sci. Vitaminol. 48. 115-119, 2002	<input checked="" type="checkbox"/>
31	Taillandier et al., "Coordinate Activation of Lysosomal, Ca <sup>2+</sup> -Activated and ATP-ubiquitin-dependent Proteinases in the Unweighted Rat Soleus Muscle", Biochem. J. (1996) 316, 65-72	<input checked="" type="checkbox"/>
32	Tawa et al., "Inhibitors of the Proteasome Reduce the Accelerated Proteolysis in Atrophying Rat Skeletal Muscles", J. Clin. Invest., Volume 100, Number 1, <del>1997</del> , pp. 197-203, 1997.	<input checked="" type="checkbox"/>
33	Tidball et al., "Expression of a Calpastatin Transgene Slows Muscle Wasting and Obviates Changes in Myosin Isoform Expression During Murine Muscle Disuse", J. Physiol. 2002;545;819-828	<input checked="" type="checkbox"/>

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34	Tischler et al., "Different Mechanisms of Increased Proteolysis in Atrophy Induced by Denervation or Unweighting of Rat Soleus Muscle", Metabolism, Vol. 39, No. 7, 1990: pp. 756-763	<input checked="" type="checkbox"/>
35	Ware et al., "Soybean Bowman-Birk Protease Inhibitor Is a Highly Effective Inhibitor of Human Mast Cell Chymase", Archives of Biochemistry and Biophysics, Vol. 344, No. 1, pp. 133-138, 1997	<input checked="" type="checkbox"/>
36	Yavelow et al., "Nanomolar Concentrations of Bowman-Birk Soybean Protease Inhibitor Suppress x-ray-Induced Transformation in Vitro", Proc. Natl. Acad. Sci. USA, Vol. 82, pp. 5395-5399, 1985	<input checked="" type="checkbox"/>

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**EXAMINER SIGNATURE**

Examiner Signature	/Michael Meller/ (05/06/2010)	Date Considered	
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- ☐ See attached certification statement.
- ☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
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**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	//Kathleen A. Tyrrell//	Date (YYYY-MM-DD)	2007-04-17
Name/Print	Kathleen A. Tyrrell	Registration Number	38,350

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